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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PATTEN, PATRICIA A	

ART UNIT	PAPER NUMBER
1654	7

DATE MAILED: 08/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,410	PARADISE, LOU	
	Examiner	Art Unit	
	Patricia A Patten	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-14 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-14 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-2, 5-14 and 18-20 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-14 and 18-19 in Paper No. 4 is acknowledged. The traversal is on the ground(s) that Group II is not patentably distinct. Because all of the distinguishing characteristics of Group II are found in the claims of Group I, Applicant's arguments are persuasive and the restriction requirement has been removed. However, the election of species remains in order for the reasons set forth in the Restriction requirement on 3/17/03. Applicant's election of Arnica Montana and Lachesis ninta is acknowledged. Applicant argues that 'the claims are entitled for consideration as a single invention since the claims are so linked together to form a general inventive concept, premised on the concept of a common special technical feature'. The Applicant is reminded that 'unity of invention' standards are only set forth in PCT practice; i.e., a PCT application, or an application in the National stage (371). The Instant application falls under neither of these categories and is thus subject to US restriction practice under 35 USC 121. Therefore, this argument is considered moot and the election of species requirement is hereby made FINAL.

Claim Objections

Claims 1, 2 and 18 are objected to because of the following informalities:

Claim 1 recites 'crotalus horridus'. In order to conform to proper Latin nomenclature for reptiles, the genus, Crotalus, should be capitalized.

Claims 2 and 18 recite 'Arnica Montana' and Prunus Cerasus' respectively. In order to conform to proper Latin herbal nomenclature, it is asked that the species, 'montana' and 'cerasus' respectively, are not capitalized.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 5-14 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2, 5-9, 12-14 and 18-20 all recite the term 'disease' without specifying exactly what disease the claim is referring to. Specifically, the claims recite 'wherein there is restricted blood flow and a reduction in motor and sensory nerve conduction velocities...'. It is unclear what diseases Applicant is referring to besides diabetic neuropathy. Further, because of the ambiguity with regard to the recitation in claim 10 which limits the 'disease' to fibromyalgia (please see *infra*) , it is further not understood what the intended scope of the term 'disease' in the Instant claims. What other diseases are these claims referring to? Clarification is necessary.

Claims 1-2, 5-14 and 18-20 either recite, or depend upon a claim which recites 'an effective amount'. The metes and bounds of this phrase are not delineated, in that it cannot be ascertained what an 'effective amount' is. Applicants have not provided any indication what an effective amount of the composition would be. Because none of the ingredients listed in the claims were known in the art for treating any of the claimed disorders, the ordinary artisan cannot rely on the state of the art to provide this information. A mere disclosure of a percentage of a constituent in a composition is not considered an 'effective amount'; i.e., the claims state 'About 0.5 to 5% by weight of a vasodilator derived from a plant'. This is deemed to read on 0.5% of a picogram. Is this an effective amount? Lacking a definition in the Specification, the ordinary artisan could not be sure. Thus, the phrase is vague and indefinite, and the ordinary artisan would have trouble determining what Applicants mean by 'effective amount'.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "fibromyalgia" in claim 10 is used by the claim to mean "a disease wherein there is restricted blood flow and a reduction in motor and sensory nerve conduction velocities", while the accepted meaning is "a disease associated with muscle pain." The term is indefinite because the specification does not clearly redefine the term. Thus, claim 10 was examined on the merits as if it were drawn to 'a method for treating fibromyalgia' without the language which states 'a disease wherein there is restricted blood flow and a reduction in motor and sensory nerve conduction velocities' because claim 10 is inconsistent with the definition of the 'disease' as recited in claim 1.

Claim 1 further states the term 'naja'. This term was not found in the art. Is this a species of plant? If it is a species of plant, is this plant documented in the art? Without any teaching in the Instant specification of what the term 'naja' means, the ordinary artisan would not be able to fully comprehend the metes and bounds of the claimed invention.

Claim 1 recites 'About 0.5 to 5% by weight of a mobilizer of white blood cell activity selected from the group consisting of Lachesis ninta, crotalus horridus....'. Here, Lachesis ninta and crotalus horridus lack antecedent basis in the claims because *Lachesis ninta* is a plant, and *Crotalus horridus* is a rattlesnake. Does Applicant mean that a particular extract or product produced from these respective species are mobilizers of white blood cells? This is unclear, and the ordinary artisan would have trouble ascertaining exactly what the claim means as it stands. It is suggested that Applicant more clearly point out what the mobilizer of white blood cells is.

Claims 1 and 20 recite 'and the remainder being filler'. The phrase 'the remainder' lacks antecedent basis in the respective claims. It is suggested that the phrase read 'wherein the remainder of the composition..' in order to provide clear antecedent basis in the claims. Further, the term 'filler' in this claim is unclear. This term is not defined in the Instant specification. The term is ambiguous: Is a 'filler' water, ointment, powder (i.e., a 'carrier'?). The term 'filler' does not have a universal meaning

in pharmacology, and is not analogous with the term 'carrier'. In order to overcome this ambiguity, Applicant is asked to more clearly state what is present in the composition.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 5-14 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to

make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Inventions targeted for human therapy bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatments. The standard of enablement is higher for such inventions because effective treatments for disease conditions are relatively rare, and may be unbelievable in the absence of strong supporting evidence. Claims drawn to pharmaceutically acceptable compositions and to methods of administering compounds to humans generally require supporting evidence because of the unpredictability in biological responses to therapeutic treatments.

In the Instant case, Applicant has claimed a method for treating a disease in a patient wherein there is restricted blood flow and a reduction in motor and sensory nerve conduction velocities. It is first noted that the breadth of the claims encompasses

treating a *disease* and not simply a symptom of a disease. According to the specification, these diseases may include fibromyalgia, diabetic neuropathy and toxic neuropathy. However, it was indicated *supra*, that the disease 'fibromyalgia' is deemed inconsistent with the Applicants definition of 'the disease' of claim 1 and therefore, the Examiner treated this claim as if it were drawn to a method for treating fibromyalgia and did not contain the language 'a disease wherein there is restricted blood flow and a reduction in motor and sensory nerve conduction velocities'. Therefore, as the claims are being treated on the merits, the Instantly recited claims are drawn to a method for treating diseases wherein there is restricted blood flow and a reduction in motor and sensory nerve conduction velocities such as diabetic neuropathy, and separately, a method for treating fibromyalgia (claim 10). The recited methods include topical administration of a composition comprising *Arnica montana* as a vasodilator, *Echinacea augstifolia* and *Lachesis ninta* (for example) as a mobilizer of white blood cell activity.

Having established the breadth of the claims, *Wands* now requires that one consider the number of working examples presented in the instant specification. It is noted that there is not a single example in the instant specification, working or prophetic, where the composition of the Instant method claims was successful in treating restricted blood flow, reduction in motor and sensory nerve conduction, or treatment of fibromyalgia or diabetic neuropathy. Since there are **no** working examples, then one must consider the guidance provided by the instant specification and the prior art of record.

It cannot be found in the art where any of the ingredients of the Instant claims have been used to successfully treat diseases such as diabetic neuropathy, fibromyalgia, or symptoms of diabetic neuropathy such as motor and sensory nerve conduction. Additionally, it is not found in the art where *Arnica montana* has vasodilating properties. Further, unpredictability with regard to the pharmacological properties of this plant is well documented in the art: Although *Arnica montana* had been alleged to treat pain, studies clearly demonstrated that *Arnica montana* was no better than placebo in pain treatment (Mayor 2/8/2003 British Medical Journal, p.1 printout). Assuming *arguendo* that *Arnica montana* does have vasodilating properties, it remains unclear how a vasodilator or 'mobilizer of white blood cell activity' will suppress any disease or condition characterized by restricted blood flow and reduction in motor and sensory nerve conduction especially lacking even one working example within the Instant specification.

Moreover, *Crotalus horridus*, the poisonous Timber rattlesnake, is not known in the art as a mobilizer of white blood cell activity (although the skilled artisan would reasonably conclude that a snake bite would release venom into the skin and provide for mobilization of white blood cells, however, the claims do not state a particular extract or venom of *C.horridus*, the claims state the snake itself), nor for any beneficial therapeutic activity toward diabetic neuropathy or fibromyalgia. *Lachesis ninta* is also not known as a mobilizer of white blood cell activity. Again, it would not be known or

expected that these ingredients would provide for any therapeutic effect with regard to diseases which impart restricted blood flow and reduction in motor and sensory nerve conduction such as diabetic neuropathy. *Rhus toxicodendron, Rhus graveloeus, Resculus hippocastanum* and *Prunus cerasus* are also not known in the art for treating any of the previously mentioned disorders.

The state of the art reflects that treatments for diseases such as fibromyalgia and diabetic neuropathy are rare:

It is well known as well that fibromyalgia is a disease which does not provide for any specific histological abnormality and may be associated with psychophysiological manifestations (Merck Manual p. 481). Because the etiologies of this disease are not well defined, treatments for fibromyalgia largely take the form of stress and depression management (p. 482). Pain associated with fibromyalgia has not been reported in the art as being manifested by blood flow restriction; on the contrary, inflammation is not present in fibromyalgia patients, which would therefore lead the skilled artisan to ascertain that blood flow is not impeded in fibromyalgia patients. The skilled artisan would not have a reasonable expectation that the composition of the Instant claims would treat fibromyalgia, especially lacking However, as it will be evaluated *infra,* the claims are also deemed non-enabled for topically treating these specific symptoms.

Additionally, it is known in the art that treatments for diabetic neuropathy is rare. Galdes et al. (US 2003/0083242 A1)disclosed that "diabetic neuropathy, unfortunately, has no effective treatment at this point in the art" save for the discovery that control of blood sugar may slow progression of the disease (p.1 [0010]). Thus, claims to a treatment for diseases such as diabetic neuropathy would need to show convincing evidence of such.

Galdes et al. explain that diabetic neuropathy is a disease of the peripheral nervous system, characterized by motor, sensory or autonomic disorders (p.1, col's 1 and 2). Thus, diabetic neuropathy is manifested by an underlying cause related to diabetes: the body's inability to transport glucose. In order to treat diabetic neuropathy, the disease would need to be treated at the primary or intermediate cause of the neuropathy. The only viable treatment, as discussed *supra*, is regulating glucose levels. Treatments for intermediate causes are not known. Applicant has not provided any scientific evidence that topical application of the composition will stabilize glucose levels. Further, the skilled artisan would not expect this to occur, since none of the individual ingredients have been shown in the art to possess this activity. It is noted that Applicants have not provided any mechanism of action of the composition of the method claims, nor have they provided evidence that treatment of restricted blood flow will treat motor or sensory nerve conduction (or fibromyalgia or diabetic neuropathy).

In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, *he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112*; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." (Emphasis added)

The high degree of unpredictability associated with the claimed method underscores the need to provide teachings in the specification that would provide the skilled artisan with specific treatment regimens that achieve a therapeutic benefit by *in vivo* therapy; however, the specification does not provide such guidance and fails to provide critical information such as dosage amounts and frequencies. Without such guidance in the specification and the lack of correlative working examples, the claims

would ***require an undue amount of experimentation involving tedious trial and error protocols. The skilled artisan would perform this experimentation lacking any predictable degree of success***.

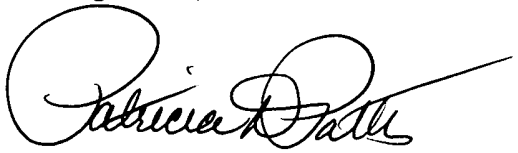
No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

August 14, 2003



Patricia Patten